In The Matter Of:

~In Re: Avaulta~

Bobbie Shull, M.D.

02/06/2013

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IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C.R. BARD, INC.
PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION: MDL NO. 2187

THIS DOCUMENTS RELATES TO:

LINDA RIZZO and RONALD RIZZO,
Plaintiffs,
vs.
C.R. BARD, INC.,
Defendant.
Case No. 2:10-cv-01224

WANDA QUEEN and GREG QUEEN,
Plaintiffs,
vs.
C.R. BARD, INC.,
Defendant.
Case No. 2:11-cv-00012

VIDEO DEPOSITION OF BOBBIE LEWIS SHULL, M.D.

February 6, 2013 - 9:14 a.m.

Mueller Law Offices

404 W. 7th Street

Austin, Texas 78701

Judith L. Leitz Moran - RPR, CCR-B-2312

A I don't know who produces some of the things we use at work, frankly. So it's quite possible because I believe our organization maybe has a contract with Covidien for certain items, but I don't know what they are.

Q Are you familiar with the federal regulations promulgated by the FDA concerning the content of instructions for use with regard to medical devices?

A I don't think I understand the question.

Q Are you familiar with the federal regulations that govern what goes into -- what types of information goes into instructions for use with regard to medical devices?

A No, I'm not.

Q Have you ever developed a training program for the use of medical devices?

A In our department we have taught courses on surgery. We began probably in the 19 -- early 1980s doing a postgraduate course on the evaluation and management of women with pelvic organ prolapse that was entirely didactic. There were no hands-on experiences of any kind.

BY MR. NORTH:

Q Well, that leads me to my next question then. I gather that you have never actually performed surgical tests with squirrel monkeys?

A I haven't personally, our lab has. So, yes, we have PhDs in the lab and physicians in the lab who do that. I have not personally done the surgeries.

Q Have you ever designed any sort of animal test for the implantation of some sort of product or device?

A Our group has. I didn't personally.

Q I'm asking about you personally.

A No, I haven't.

Q You've never developed a protocol for an animal test?

A No.

Q You've never performed an animal test personally?

A No.

Q Have you ever witnessed animal testing taking place?

A How do you mean witnessing? The implantation of a product or the explantation

of a product?

Q Right.

A No.

Q And to the extent that's done in your group, that's done in the laboratory with other physicians and PhDs?

A That's correct.

MR. NORTH: If we could mark this as the next exhibit. Is that No. 5?

THE COURT REPORTER: Uh-huh.

(Defendant's Exhibit 5 marked.)

MR. GARRARD: Do you got one that my old eyes can read?

MR. NORTH: We are all in the same boat, Mr. Garrard.

BY MR. NORTH:

Q Doctor, is this an article that you had prepared in the past?

A Yes.

Q And when was this published?

A December 1994.

Q This did not have to do with the implant of any mesh product, did it?

A In this series of 62 women, we used native tissue and suture material.

I don't -- I didn't know the names of the products.

Q Now, to your knowledge, have we now discussed all of your publications with regard to mesh products for the treatment of pelvic organ prolapse?

A I hope so.

Q Okay.

MR. GARRARD: Do you need to look at the new CV?

MR. NORTH: Well, he can always --

MR. GARRARD: Well, I'm just -- we may --

MR. NORTH: -- add something. I'm just asking to his knowledge now.

BY MR. NORTH:

Q Let's talk a little bit about your retention in this case as an expert witness.

Now, I certainly understand -- you know, appreciate your expertise as an OB-GYN and in the gynecological surgery area. But I want to see if we can be clear about areas where you're not an expert. And I asked you about your training and expertise in some of these areas earlier.

But would you agree that you are not an expert in developing warnings and labels for medical devices?

A I have never developed a warning or a label. I don't intend to do that. And I don't know the process for doing it, so I would not claim to be an expert in that area.

Q And you are not an expert in the design of medical devices, are you?

A No, I've never designed a device.

Q And you are not an expert in biomaterials?

A No.

Q And are you an expert in biocompatibility?

A No.

Q And are you an expert in materials manufacturing?

A No.

Q Are you an expert in the manufacturing processes for medical devices?

A No.

Q And we talked about your training in pathology. Would you consider yourself an expert in pathology?

A No.

Q Would you consider yourself an expert in toxicology?

A No.

Q Would you consider yourself an expert in the marketing of products?

A No.

Q Would you consider yourself an expert in the marketing of medical devices?

A No.

Q Do you deal with sales representatives from various medical device manufacturers as a part of your practice?

A Sometimes.

Q Do you deal with any medical device or any sales representative from Bard?

A Can you tell me what dealing with means?

Q With any type of product.

A Do I sit down and discuss the products with them?

Q Uh-huh.

A Perhaps I have. I certainly wouldn't do it with any frequency.

Q Do you know the name of any Bard

A I don't believe so.

Q And you weren't shown the deposition of Tad Nations?

A I don't believe so.

Q You weren't shown the deposition of Melissa Johnson?

A I recognize that name. I don't know that I saw her deposition.

Q The only depositions you've seen are the ones that Mr. Garrard and Dr. Johnson showed you, correct?

A You mean Dr. Thompson?

Q I'm sorry, Dr. Thompson.

A I believe that would be true.

Q And they selected the depositions to show you, correct?

A I presume they did.

Q I mean, you didn't come up with a list of the employees yourself that you wanted to see their depositions, did you?

A No.

Q Okay. As a part of your work in this case, have you gone back and looked at any regulations put out by the FDA that might govern these products?

A The 510(k) -- I've looked at the form for 510(k) submission.

Q And that was given to you by the Plaintiffs' attorneys, correct?

A Yes.

Q Have you looked at any regulations from the FDA, though?

A I have not gone to an FDA website or obtained any information from the FDA regarding how to submit a proposal or what's included or the process for it.

Q Well, the FDA regulations go beyond how to submit a proposal. So have you looked, as a part of your work at this case, at any regulations put out by the FDA that might be applicable to this product?

A No.

Q Have you reviewed the 2008 and 2011 public health notifications put out by the FDA?

A Regarding?

Q Pelvic mesh products.

A The warnings about pelvic mesh products?

Q The public health notification.

A Yes, I have.

Q With regard to medical devices, do you know what percentage of medical devices go through clinical studies before they're introduced to the market?

A No.

Q Do you know with regard to medical devices whether more products go through clinical studies or don't go through clinical studies before they're introduced to the market?

A I do not know that.

Q Do you know whether Bard was required to conduct clinical studies on Avaulta before introducing it to the market?

MR. GARRARD: Required? In terms of the form of your question, required by what or whom?

BY MR. NORTH:

Q By FDA rules and regulations.

A Do you mind repeating the question for me?

Q Do you know whether Bard was required under FDA regulations to perform clinical studies on Avaulta before it was introduced to the market?

A I do not know that. My presumption is if they're using the predicate device as the mechanism for getting the clearance, that there may have been no requirements.

Q How long do you believe it would have taken to conduct a clinical study of Avaulta, or do you know?

A I can answer that in general. It depends on what you would like to know about it. So depending on the knowledge you hope to acquire, there would be varying time intervals.

If it's a question about indications and patient selection, that may take a shorter time period.

If there are questions about the morbidity associated with the operation itself or the morbidity in the first six weeks following surgery, that would take a relatively defined time period depending on the number of patients required for you to draw conclusions from.

If you're talking about the long-term consequences of a product, in this case we have previous information from reports on sacral colpopexy, for example, which teaches us that

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~In Re: Avaulta~

Robert Shull, Vol. II

02/28/2013

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FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

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IN RE: C.R. BARD, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION:	MDL NO. 2187
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LINDA RIZZO and RONALD RIZZO, Plaintiffs, vs. C.R. BARD, INC., Defendant.	Case No. 2:10-cv-01224
WANDA QUEEN and GREG QUEEN, Plaintiffs, vs. C.R. BARD, INC., Defendant.	Case No. 2:11-cv-00012

VOLUME II

VIDEO DEPOSITION OF ROBERT L. SHULL, M.D.

February 28, 2013 - 8:53 a.m.

Mueller Law Office

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Judith L. Leitz Moran - RPR, CCR-B-2312

CAROLYN JONES,

Plaintiff,

vs.

C.R. BARD, INC.,

Defendant.

Case No. 2:11-cv-00114

DONNA CISSON and DAN CISSON,

Plaintiffs,

vs.

C.R. BARD, INC.,

Defendant.

Case No. 2:11-cv-00195

NANCY SMITH and JOHN SMITH,

Plaintiffs,

vs.

C.R. BARD, INC. and SOFRADIM PRODUCTION SAS,

Defendants.

Case No. 2:11-cv-01355

Q Prior to your involvement in this case, have you read the instructions for use of any other manufacturer's mesh kit for transvaginal use?

MR. GARRARD: Objection, that's already been asked and answered last time.

A I think the same answer applies. I would go by the exhibits at scientific meetings, look at what was available, and would watch the DVDs, listen to the representatives, and read some of the literature, including IFUs, but I do not know for the specific products.

BY MR. NORTH:

Q Doctor, one statement you make on Pages 28 and 29 of your report is the suggestion that the IFU was deficient because it did not warn or teach about patient selection; is that correct?

A Yes.

Q Doctor, isn't the notion of patient selection, doesn't that involve a medical judgment?

A Based on all of the factual information you have, yes, it does. My

contention here is the doctor doesn't have all the medical information needed to make a decision.

Q But you would agree that a medical device manufacturer can't tell a doctor which patient should and should not have -- no, let's strike that.

You would agree that a medical device manufacturer should not be making medical judgments as to patient selection, correct?

A The manufacturer should provide a physician enough information so the physician can make an informed decision, relay that to the patient and have the patient participate in a decision about the use of a medication or a device.

My contention is that there wasn't enough information provided to anyone to educate the physician or the patient about patient selection or contraindications.

If I could give you an example of something that has multiple meanings.

The IFU only states that Avaulta products are contraindicated for patients who are pregnant or may become pregnant. That's

clear. Have urinary tract infection. That is clear. Have an infection in the operative field. That is clear.

Or patients in a period of growth because the mesh may not stretch significantly. That is extremely unclear. What is a period of growth?

That's only an example. But my real concern isn't about the specific things that were said, it's about the things that were not said. There have to be reasons not to use implantable product in addition to these that have been given.

Any reasonable doctor would agree with that. Any reasonable patient would like to know has the doctor evaluated them to be a satisfactory candidate for a drug, a product, or a procedure.

MR. NORTH: Move to strike as nonresponsive.

BY MR. NORTH:

Q Doctor --

MR. GARRARD: It was responsive.

BY MR. NORTH:

Q -- at some point in your report on

Page 25 you suggest that a surgeon needs to be informed of the risks and benefits and be supplied with the supporting data. Suggesting to me that you believe the IFU should contain supporting data regarding risks and benefits; is that correct?

A Yes.

Q But you are not aware of whether there's any FDA requirement regarding the insertion of supporting data in an IFU, are you?

A I do not know if the agency who approves the IFU needs supporting data nor do I know if it's a requirement to provide it to the user. My point is, you can't intelligently use something without this information.

Q Can you recall any IFUs for other products that you've used that have supporting data for their risks and benefits in the IFU?

A I don't know the answer to that. The answer is I do not know.

Q The question was, do you recall, so --

A I do not. I have not seen that in another IFU.

Q Okay. You also state at one point --

MR. GARRARD: Wait a minute.

(Off the record.)

BY MR. NORTH:

Q Okay. You state that the IFU should say that mesh products should not be used in women with a history of chronic pelvic pain.

Do you recall saying that?

A I believe I did.

Q Are you aware of whether any of the Bellwether Plaintiffs whose records you reviewed had a history, prior history, of chronic pelvic pain?

A I believe that Donna Cisson had an abdominal hysterectomy and oophorectomy some 10 to 20 years prior to the implantation of the device. And I believe that one of the indications in the record was for pelvic pain.

Q Do you know whether that was chronic pelvic pain?

A I'm going to look that up.

I'm looking for the specific reference in the records. It's going to take me just a moment to find that.

Well, I know that it is not